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| 10/749,563 | 01/02/2004 | Chung-Yu Yang | YANG3057CIP2/REF | 8784 |

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| EXAMINER | |
|---|---|
| KOHARSKI, CHRISTOPHER | |
| **ART UNIT** | **PAPER NUMBER** |
| 3763 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/749,563 | YANG, CHUNG-YU | |
| | Examiner | Art Unit | |
| | Christopher D. Koharski | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16 and 17* is/are allowed.

6)☒ Claim(s) *1-9,14 and 15* is/are rejected.

7)☒ Claim(s) *10-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

Examiner acknowledges the reply filed 8/14/2007 in which claim 1 was amended. Currently claims 1-17 are pending for examination in this application.

### *Specification*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title change is suggested: Examiner suggests additional language drawn to the needle unit retraction mechanism.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 14-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,074,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

**Application claim 1 requires:**

A safety syringe, comprising: a syringe barrel including a barrel body with a front opening, a rear opening, a front end wall and a rear end wall, wherein a cross-sectional area of said front opening is smaller than a cross-sectional area of said rear opening, a spacer portion is integrally disposed within said barrel body and is penetrated by said front opening ; a flexible holder-supporting seat being disposed movably within said syringe barrel and on said spacer portion, wherein said flexible holder-supporting seat includes a central hole formed therethrough ; a needle unit including a needle holder and a needle penetrating said needle holder, said needle unit is disposed movably within said front end wall, said needle holder being sleeved by said central hole of said flexible holder-supporting seat on said spacer portion, wherein a rear opening is formed in said rear end of said needle holder, said needle penetrates said needle holder and said spacer portion and is projected from said front opening; a plunger including a front end with a front opening and an inward flange, a rear end and a plunger body formed between said front end and said rear end, a cross-sectional area of said front opening being larger than an external diameter of said needle holder, said plunger being disposed movably within said syringe barrel; and a flexible sealing member sleeved by

said inward flange to seal said front opening of said plunger, said flexible sealing member combining with said needle unit after said plunger being pushed to be close to said flexible holder-supporting seat, said flexible holder-supporting seat being sleeved on said spacer portion, and then said needle unit being released from said flexible holder-supporting seat due to said plunger, wherein said flexible sealing member is propped by said needle holder, and then said flexible sealing member is released from said inward flange to be automatically retracted into said plunger body due to a pressure.

**While patent claim 1 requires:**

A safety syringe comprising: a syringe barrel having a front end wall with a front opening, and a rear end wall with a rear opening; a plunger disposed movably within said barrel and having a front end and a rear end that extends from said rear opening in said syringe barrel; and a needle unit extending through said front opening in said syringe barrel and including a central bore formed therethrough, a needle holder that is formed with a rear opening, and a needle that is connected fixedly to said needle holder at a rear end and that is exposed outwardly from said front opening in said syringe barrel; wherein said syringe barrel includes an annular flexible holder-supporting seat disposed movably within said syringe barrel and sleeved around said needle holder, aid holder-supporting seat having a central hole formed therethrough, an outer periphery that is in frictional contact with an inner surface of said syringe barrel in such a manner that a liquid-tight seal is established therebetween, and an inner periphery that is in frictional contact with an outer surface of said needle holder in such a manner that a

liquid-tight seal is established therebetween; wherein said plunger has an open front end that is formed with a front opening, a rear end wall, and a front end portion that is formed with an inward flange extending integrally, radially, and inwardly therefrom; wherein said safety syringe further comprises a flexible sealing member disposed movably within said front end portion of said plunger so as to define a vacuum chamber in said plunger between said sealing member and said rear end wall of said plunger, said inward flange being sleeved around and clamping said sealing member in said plunger so as to prevent movement of said sealing member relative to said plunger, thereby permitting synchronous rearward movement of said sealing member and said plunger when said plunger is pulled rearward relative to said syringe barrel, said sealing member having a holder-retaining front portion that is disposed behind and that is spaced apart from said needle holder, and a sealing rear portion for closing said front opening in said plunger; wherein said needle unit has a spacer portion that is formed integrally between said needle holder and said needle and that is sized to prevent movement of said spacer portion into said front opening in said syringe barrel such that said needle holder is clamped within said holder-supporting seat at a position that is spaced apart from said front end wall by a predetermined distance; wherein said holder-retaining front portion of said sealing member moves forward to retain said needle holder thereon, when said plunger is moved forward within said syringe barrel to push said holder-supporting seat forward, such that said holder-supporting seat separates from said needle holder so as to permit automatic rearward movement of an assembly of said sealing member and said needle unit within said syringe barrel due to

negative pressure produced within said plunger, thereby retracting said needle into said syringe barrel.

Thus it is apparent that the application claims are broader than the patent claims and the subsequent patented independent and dependant claims 2-5 encompass application claims 2-9 and 15. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

***Allowable Subject Matter***

Claims 16 and 17 are allowed.

Claims 10-13 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments, see remarks, filed 8/14/2007, with respect to claims 10-13 and 16-17 have been fully considered and are persuasive. The rejection of claims 10-13 and 16-17 has been withdrawn.

Applicant's arguments filed 8/14/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the amended claim is patentably distinct over the 7,074,207 patent because of the spacer portion integrally

within said barrel body and a flexible sealing member being sleeved on said spacer portion.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the described flexible sealing member (col 5, ln 10-25) of the disclosed patent and the needle unit (col 5, ln 25-32) discloses the device as claimed. Making an element integral would have been obvious to one having ordinary skill in the art at the time the invention, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). Additionally, the "spacer portion" of the present claim language can be equated with the safety syringe holder supporting seat (col 4, ln 55-70) and the needle "crook" can be equated to the integral needle spacer portion (col 5, ln 25-32), since the word crook has no relative structural definition.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

***Suggested Allowable Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further describing the **"crook" or "spacer element"** to the barrell with structure that overcomes the US 7,074,207 patent.

***Conclusion***

The closest prior art made of record and not relied upon is considered pertinent to applicant's disclosure: 5,997,512 (see PTO 892).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/27/07

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